EXHIBIT B

ABBOTT LA)RATORIES RESEARCH DEPARTMENT

ROJECT Hell conto fros (P. OR CODE NO. Blended mg)	ind long	This is the
(P. OR CODE NO. Deliala mys		first demon.
•	PIN 55.82 88.36 87.54 93.57 93	Stration of a
	9	Combuntin
	Ag Assay Mean counts 08/24/00 78 4408.63 681.5 2845 4708.5 5071 4258 2853	antibody/Ag
	* *	test for HCV.
	P/N 8.64 1.23 8.36 37.48 0.52 0.44 0.43 0.43	
		cont. on pse #16
Blended Up and Blended conjugate Blended Up and Blended conjugate Up: HC31 (DF=3, Coaling cone: 200ug/ml) + C11-14 (0.09% 0.4um) Up: HC31 (DF=3, Coaling cone: 200ug/ml) + C11-14 (0.09% 0.9mm) Conjugate: C11-10 (100ng/ml 1:16) + 8452B (1/5dilution in HiV combo CD) SDB: 6452Q Up diluent: 18498 HCv Ab assay up diluent SIA configuration: HCV	Ab Assay Mean Counts 08/28/00 33952 3990.17 4818.75 38800.87 147307.5 1704.5 1667.5	
ate C11-14 ((1/5dii wash :1	£	
onjug (9/828 (9/828 (1081)	PIN 1.17 1.10 1.11 1.10 1.11 1.10 1.11 1.10 1.11 1.10 1.11 1.10 1.11 1.10 1.11 1	
Luka 1 146 CO 116 > 40 Deviot 5 By up dill	P.IN 2.17 0.91 1.41 11.91 10.28 3.92 3.92 1.10 2.38 2.38 2.38	
Blenc Ing confing rong/ml r wash		
21:28:16 Up and 11-10 (10 ag transfe 8498 HC\	Combo Assay Mean counts 1712.5 780 1110 8410 8410 8410 8104.5 3084.5 3084.5 258.5 358.5 358.5 3001 2172.5 3707	
Decision 21:29:16 Luisko Blended Up and Blended conjugate Up: HC31 (DF=3 Coating conc; 200ug/ml) + C11-Conjugate: C11-10 (100ng/ml 1:16) + 6A52B (115 Up diliuent: 18498 HCv Ab assay up diluent S/A configuration: HCV	SubB 1923 852 745 1083 9035 8237 3639 5280 699 1773 3120 2280 3120	
	SubA 1502 808 775 7719 7719 7719 7872 2550 2550 2552 2552 2552 2552 2552 25	
	- ¥	
	Samples PC (Ab) NC (Ab) Panel A Panel A Panel A Po JV 04828 PC JV	
<u> </u>	Sample PC (/ NC (/ NC)(/ NC (/ NC)(/ NC (/ NC)(/ NC)(/ NC (/ NC)(/ NC	
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PROJECT HON 2000 PSSM	
PROJECT HU combo Kasing EXP. OR CODE NO. Cont. Stone page #8.	
	!
DESCRIPTION OF PANEL MEMBERS -	
NC - negative control - pooled plasma individually screened as negative for HCV antibodies by a commercialized assay- Code: 6A52E. Prism HCv Ab Assay Negative Calibrator. PC - positive control - pooled anti-HCV positive plasma diluted in negative control . Code: 6A52F. Prism HCV Ab Assay Positive Calibrator.	
99800 - Plasma(human) Recalcified Negative Bulk.	
Panel A - an anti-HCV positive plasma that has been diluted in negative control to provide a mid	
range sample to cutoff in the PRISM antibody assay.	
E2 1/20 - an anti-HCV positive sample that has been diluted in negative control - the E2 antibody panel was utilized to titrate the potency of HCV E2 antigen coated microparticles	
Promed 9992161 - an antibody positive sample obtained from ProMeDx (Plainville, MA)	
PC JV 16929 - Sero-Tec HCV RNA positive human plasma . — PC P JV17220 · Sero-Tec HCV RNA positive human plasma .	to the second
SeraTec Panel members 3-9 - serial bleeds obtained from a plasma donor identified at SeraTec as being anti-HCv negative and HCV antigen positive.	<u> </u>
A panel of specimens previously characterized as having antibodies to HCV or being negative for antibodies to HCV but positive for HCV RNA and HCV antigens were tested in a preliminary HCV combination antibody.antigen test.	
Reagents utilized in combo test Microparticles specific for HCV antigen detection (up's coated with C11-14 as described on RB: 67093 page 100) and microparticles specific for HCV antibody detection (up's coated with HCV recombinant protein HC 31 as described on RB: 68160page 2) were blended to produce a solid phase that would allow simultaneous detection of HCV antibodies and HCV antigens in a single reaction well. (The blended microparticles contained 0.19% solids, representing a mixture of 0.09% up's coated with C11-14 and 0.1% coated with HC31). The conjugates were also a mixture of two separate acridinium labeled proteins. Acridinium labeled C11-10 was utilized for HCV antigen detection (recognizing HCV antigens captured on the C11-14 microparticles) and an acridinium labeled monoclonal antibodies against biotin -labeled gaot anti-human lgG (presented as a pre-complex - see RB: 52226m301) was utilized to detect human anti-HCV lgG bound to the HC-31 coated microparticles.	Jesoch 2 to 1
Results	2 2
The panel described above was run on 3 different PRISM-based assays. One of the assays detected HCV antibodies, a second test detected HCV antigens and a third test (the combo assay) detected both HCV antibodies and HCV antigens. Sampels have a positive to negative ratio (P/N) ratio of 3.0 or greater were considered positive. The data presented in the table on RB68160page 8 indicate that the combo assay allows detection both of antibody positive samples (e.g. panel E2 1/20, ProMed 9992161, PC JV 016929 and PC JV 17220) and HCV antigen positive samples (Sera Tec panel members 5-9). Thus, this single combo assay performed in a single reaction well detects most of the samples that were positive in two separately performed assays, the HCV antibody test and the HCV antigen test. This is the first demonstration of a combo HCV antibody / HCV antigen test at Abbott Laboratories, and is the first example of the HCV antibody /antigen combo test ideas presented in Redbook 61,959: pages 1-8. Other iterations of the HCV combo test will be presented over the next several weeks/months.	
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PROJECT HW comb	o fram.	*		
EXP. OR CODE NO.				
Title: HCV combo As	say: Blended up a	and Blended co	onjugate :11-14 coated ups together and c	
, aHigG Acr* conjugate together for				
Materials and Samples RB: 68160001 and 68160011.	ell-14-Ab	conted us	bs 4 for 16 Delection) for 12 Netection)	-
Preparation: Add Avidin 11-28 (df = 20) and NS: Add conjugate c11-10 (50ng/ml) ar	BNS4 (df = 10) and c nd aHigG Acr* (10ng	11-14 (0.09% se /ml)	eradyn) `	_
Results:	k			
144 00 NG2NG4		aC) 9 12		
HCV Combo (11-28, NS3NS4,	U 1 - 14 U 1-10, dF	90,012		
Conclusions: The combo assay successfully dete	ected all the Ab pos. s	samples and Ag po	ositive samples.	_
Next Steps: Dilute the AhlgG conjugate to 7ng/r	nl and 2 ng/ml			_
1023 6 A HCV COMBO 11-28,NS3NS4 C11-14 C11-10 AHIGG	N/A	09/12/00 14:30:02	2 L JIANG	
		re Bio-11-28(Df=20)+ NS jugate: c11-10(5ong/ml) ransfer. HIV Ag Devlot5, SDB: HC	ombo Assay 53NS4 HCV Ag (DF=10)+ C11-14(0.09%) + aHigG Acr*(10ng/ml) Final wash: HCV Ag final wash prep 8/1/2000 V Ab (6A52Q) 23) configuration: HCV	
 -	PC (Ab) PC (Ag) PC(Ag) PC(99800) E2 1/20 ProMed 9990196	SubA SubE 3454 3656 5303 6014 4288 3722 637 831 12480 13097	3555 4.84 5658.5 7.71 2 4005 5.46 ************************************	
	9990164 9990162 9990212 Sero-Tec panels #3 4	10060 13925 956 2347	te was added 10060 13.71 13925 18.97 956 1.30 2347	•
	5 6 7 B	3400 4673 4265 3045	3400 4573 4673 5.23 4265 5.81 3045 4.35	
	*Materials: Code/List/Desc/	Lot see RB: 68160		
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11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 22 458 454.00 11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 22 458 454.00 11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 22 458 454.00 11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 275 275 277 27	XP. OR C	ODE NO	mt. flor	n page or	. 1				
11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 22 458 454.00 11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 22 458 454.00 11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 22 458 454.00 11-28-NS3NS4-C11-14 50ng/ml -7ng/ml NC 275 275 277 27		•	•						
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Ups Conjugate 11-28+NSNR4+C11-14 50ngmi + 7ngmi Cil Ti V-H46 * E2 (1/20) 7755 7804 7778.50 1713 PEC (Ag) 4627 4627 4670 5977 PEC (Ag) 4627 4627 4670 5977 PEC (Ag) 4627 4627 4671 18.76 980212 7878 15.15 980212 7	1023	6	A	N/A	09/15/00	11:10:02	L JIANG		
## 11-28-HS3NS4-C11-14 Songrint - Traignt Songrin		/ERSION							
## 11-28-HS3NS4-C11-14 Songrint - Traignt Songrin									
## 11-28-HS3NS4-C11-14 Songrint - Traignt Songrin									
11-28-NS3NS4-C11-14 50ng/mi - 7ng/mi CII-0 - MLG - Proceedings - Proceed		ume	Conjugate					P/N	
SNATURE PC (Ag) 462 462 4657 4651 16.76 8980186 8980186 8980186 8980186 8980186 8980186 8980186 8980186 8980186 8980186 8980186 8980186 81133 5133 11.31 1257 1257 2.77 1267 2.77 1267 2.77 1270 2.77 1270 2.77 1280 8880186 8878 11.35 11.31 11.31 11.31 11.32 1287 2.277 2.477 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.497 2.498 2.	4	44 20 (NICZNICALC11-14	50ng/ml + 7ng/ml	E2 (1/20)	7753	7804	7778.50		
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\$ 2870 2870 5.35 5 5.35 1.32 1.32 1.32 1.32 1.32 1.32 1.32 1.32			:	Sero-Tec panel #3	1257		2640	5.81	
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2 2 214 2514 5.76 4 2701 2501 5.55 5 2343 4443 9.79 7 8147 8147 17.94 2ng/ml 7ng/ml 11-28+NS3NS4+C11-14 50ng/ml + 2ng/ml 22 (1/20) 2631 2879 2855 00 10.92 17.1 9 PC (Ag) 2013 4099 4156.00 15.89 9.7 9 PC (Ag) 2013 4099 4156.00 15.89 9.7 9 S985192 2249 3249 8.60 15.99 9985192 1918 1918 1918 7.33 11.3 9985192 1918 1918 1918 7.33 11.3 9985192 2290 2299 8.79 4 2293 2299 8.79 4 3002 3002 11.48 6.3 5 5 5112 19.55 10. 6 SHI HCV sero 907 #1 3754 3754 14.36 12. 8 BBI HCV sero 907 #1 3754 3754 14.36 12. 9 1440 2404 9 19 5.1 9 14743 1743 6.67 5.5 9 177 1566 1566 5.99 17				BBI HCv sero 907 #1	5595		5595		•
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Ups Conjugate NC 277 246 2615. 11-28+NS3NS4+C11-14 50ng/ml + 2ng/ml E2 (1/20) 2:281 2879 2:855.00 10.92 17.1 PC (Ag) 4213 4099 4156.00 15.89 9.7 PC (Ag) 4213 4099 4156.00 15.89 9.7 9990212 2773 2773 10.60 15.7 9996196 2249 2249 8.60 15.9 9996196 1918 1918 7.33 277 4 2299 3002 11.48 6.1 5 5 5112 5112 19.55 10. BBI HCV sero 907 #1 3754 3754 14.36 12. BBI HCV sero 907 #1 3754 2230 8.53 5.5 3 2230 2230 8.53 5.5 4 2404 2404 9.19 9.5 5 1743 1743 6.67 5.5 5 1743 2084 7.97 9.9 7 1566 5.99 17				•					
Ups Conjugate NC 277 245 261-50 10.92 17.1 11-28+NS3NS4+C11-14 50ng/ml + 2ng/ml E2 (1/20) -2831 2879 2655.00 10.92 97. PC (Ag) 4213 4099 4156.00 15.89 97. PC (Ag) 4213 4099 4156.00 15.89 97. PC (Ag) 4213 4099 4156.00 15.89 16.1 9990212 2773 2773 10.60 15.89 999162 2249 2249 8.60 15.3 999163 2249 1918 1918 7.33 11.3 S667 46 2888 2279 2299 8.79 8.89 5 3002 3002 11.48 6.3 6 5 5112 5112 19.55 10. 6 6 5112 5112 19.55 10. BBH HCV sero 907 #1 3754 3754 41.36 12. BBH HCV sero 907 #1 3754 3754 41.36 5.5 2 230 2230 8.53 55. 3 2230 2230 8.53 55. 5 1743 1743 6.67 59. 6 2084 2044 919 55. 5 1743 1743 6.67 9.9 6 2084 2084 7.97 9.9 7 1566 1566 5.99 17				•				2ng/ml	7ng/ P/N
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9996164 1918 1918 7.33 11 9996164 1918 1918 7.33 11 \$	-		. 4	9990212	2773			8.60	15.1
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BBI HCV sero 907 #1 3754 3754 14.36 12. BBI HCV sero 907 #1 3754 3754 14.36 55. 2 3 2230 2230 8.53 55. 4 2404 9 19 9 5.1 4 2404 9 19 9 5.1 5 1743 1743 6.67 5. 6 2084 2084 7.97 9.7 7 1566 1566 5.99 17				4	2299		2299	8.79	6.3
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ABBOTT LABORATORIES BOOK NO. 68,160 RESEARC DEPARTMENT

							1		Data at we demonstrates on seven member seroconversion panel, that HCV RNA and HCV Antigens can be detected from the first bleed date through the sixth bleed date, but the seventh bleed date is negative for HCV antigen. The antibody tests Ortho 3.0 and Abbott 3.0 failed to detect antibodies in the first five bleed dates (throught)		
			Roche Amplico RNA	3 x 10e6	2 x 10e6	1 x 10e6	1 x 10a6	Pu	d from the rtho 3.0 a	·	
	V907)	-	Abbit Ar Only Tri	25.68	17.88	15.98	7.90	0.70	an be detecte tibody tests O		
r:	nel (PH		Certito data Conjug@2 ng/ml	14.4	12.9	9.2	8.0	6,0	V Antigens cigen. The an	•	: —
A, INC	sion Paı	4	Combo data Cott/@7 ne/nt		6.0	6,0	9.8	18.0	RNA and HC for HCV ant		
OSTON BIOMEDICA, INC.	Anti-HCV Seroconversion Panel (PHV907)	HCV Genotype 1A	ORYSO RCV SO	0.0	0.0	0.1	1.0	>5.0	Data above demonstrates on seven member seroconversion panel, that HCV RNA and HCV Anthrough the sixth bleed date, but the seventh bleed date is negative for HCV antigen. failed to detect antibodies in the first five bleed dates (through) The combo test detected exposure to HCV for all seven bleed dates.		
BION	"V Ser	V. Gen	ABBOTT TO HCV S/CO	0.1	0.1	0.2	1,4	>5.0	onversion p venth bleed ites (or all seven		
	nti-HC	HC	Day No.	0,	7	13	21	164	Data at we demonstrates on seven member seroconver through the sixth bleed date, but the seventh failed to detect antibodies in the first five bleed dates (
BOST	A		Bleed		++		. 		n seven me bleed date, t the first fi exposure		
	,		Panel. Member	PHV907-1 PHV907-2	PHV907-3	PHV907-4	PHV907-6	1-10aA	onstrates or th the sixth ntibodies ir t detected		
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ABBOTT LABORATORIES RESEARCH ['ARTMENT

PROJECT	PRISM HO	CV Ag/Ab combo	
EXP. OR CODE NO.	Hev e	ombo Assay Random Donor Po	pulation_
Neag	ats: Same	en hop # 68/60017.	
		5/CO 6.57 4.98 0.31 0.30 0.30 0.37 0.37 0.38 0.39 0.39 0.39 0.39 0.39 0.39 0.39 0.39	
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	nbo Ass	P/N 15.30 11.66	
	тыма НСV Combo Assay Population	Mean 37955 246 246	
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